

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC.,
Petitioner

v.

CELGENE CORPORATION,
Patent Owner

Case IPR2023-00512
U.S. Patent No. 8,846,628
Issued: September 30, 2014

Title:

ORAL FORMULATIONS OF CYTIDINE ANALOGS AND METHODS OF USE THEREOF

**PETITIONER'S SECOND SET OF OBJECTIONS TO
PATENT OWNER'S EVIDENCE PURSUANT TO 37 C.F.R. § 42.64**

Petitioner's Second Set of Objections to Evidence

Pursuant to 37 C.F.R. § 42.64(b)(1), Petitioner Apotex Inc. ("Petitioner")

submits the following objections to evidence served by Celgene Corporation ("Patent Owner") with Patent Owner's Response ("POR") (Paper No. 15), in the above-captioned proceeding. These objections are timely under 37 C.F.R. § 42.64(b)(1) because they are being filed within five (5) business days of service of evidence to which these objections are directed. Petitioner's objections provide notice to Patent Owner that Petitioner may move to exclude these exhibits under 37 C.F.R. § 42.64(c). Petitioner's objections apply equally to Patent Owner's reliance on the exhibit in any documents concurrently-filed with the exhibit or any subsequently-filed documents.

In this paper, a reference to "FRE" means the Federal Rules of Evidence and "628 patent" means U.S. Patent No. 8,846,628. Exhibit descriptions provided in Table 1 are from Patent Owner's exhibit list and are used for identification purposes only. The use of an exhibit description does not indicate that Petitioner agrees with that description or characterization of the document.

Notwithstanding these objections, Petitioner expressly reserves the right to rely on any evidence submitted by Patent Owner, including on the ground that such evidence constitutes a party admission.

Petitioner incorporates by reference and reiterates, as if expressly stated herein, all objections previously served on Patent Owners on August 3, 2023.

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Petitioner objects to Exhibits 2051-2054 as incomplete, lacking relevance, and because any probative value is substantially outweighed by the danger of undue prejudice (due to confusing the issues, misleading the fact finder, undue delay, wasting time, and/or needlessly presenting cumulative evidence). *See* FRE 106, 401, 402, and 403.

Petitioner further objects to Exhibit 2051, "Expert Declaration of Cory Berkland, Ph.D." Petitioner objects to ¶¶ 30-32, 34-38, 40-41, 43-45, 47, 70-85, 88-98, 100-104, 106-107, 109-115, 118-124, 126-134, 136-144, 149 of Exhibit 2051 and all paragraphs that rely on those paragraphs. These paragraphs lack a disclosed basis of sufficient facts or data (FRE 705; 37 C.F.R. § 42.65), are not based on sufficient facts or data (FRE 702), and/or are not the product of reliable principles and methods (FRE 702). Additionally, Petitioner objects to the above referenced paragraphs of Exhibit 2051 and all paragraphs that rely on those paragraphs as misleading, incomplete, and lacking relevance and because any probative value is substantially outweighed by the danger of unfair prejudice, confusing the issues, misleading the fact finder, undue delay, wasting time, and needlessly presenting cumulative evidence (FRE 106, 401, 402, and 403).

Petitioner further objects to ¶¶ 1-29, 42, 45-49, 51-60, 70-74, 94, 120, 122-126, 135, 145-146, 150-151 of Exhibit 2051 and all paragraphs of any declaration that rely on those paragraphs. These paragraphs are irrelevant (FRE 401 and 402),

Petitioner's Second Set of Objections to Evidence and any probative value is substantially outweighed by the risk of undue prejudice and/or confusion (FRE 403).

Petitioner further objects to ¶¶ 29-31, 45, 47, 52-53, 98, 119-120, 144 of Exhibit 2051 and all paragraphs of any declaration that rely on those paragraphs. These paragraphs rely on out of court statements for their truth, thus constituting impermissible hearsay. *See* FRE 801-804.

Petitioner further objects to Exhibit 2052, "Expert Declaration of George M. Grass IV, Ph.D." Petitioner objects to ¶¶ 26, 39-46, 48-60, 62-77, 79-87, 92-97 of Exhibit 2052 and all paragraphs that rely on those paragraphs. These paragraphs lack a disclosed basis of sufficient facts or data (FRE 705; 37 C.F.R. § 42.65), are not based on sufficient facts or data (FRE 702), and/or are not the product of reliable principles and methods (FRE 702). Additionally, Petitioner objects to the above referenced paragraphs of Exhibit 2052 and all paragraphs that rely on those paragraphs as misleading, incomplete, and lacking relevance and because any probative value is substantially outweighed by the danger of unfair prejudice, confusing the issues, misleading the fact finder, undue delay, wasting time, and needlessly presenting cumulative evidence (FRE 106, 401, 402, and 403).

Petitioner further objects to ¶¶ 1-15, 25-26, 31-34, 36-38, 91-92, 96, 99-100 of Exhibit 2052 and all paragraphs of any declaration that rely on those paragraphs. These paragraphs are irrelevant (FRE 401 and 402), and any probative value is

Petitioner's Second Set of Objections to Evidence substantially outweighed by the risk of undue prejudice and/or confusion (FRE 403).

Petitioner further objects to ¶¶ 15, 26, 92, 96-97 of Exhibit 2052 and all paragraphs of any declaration that rely on those paragraphs. These paragraphs rely on out of court statements for their truth, thus constituting impermissible hearsay. *See* FRE 801-804.

Petitioner further objects to Exhibit 2053, "Expert Declaration of William G. Blum, MD." Petitioner objects to ¶¶ 21, 24-40, 47 of Exhibit 2053 and all paragraphs that rely on those paragraphs. These paragraphs lack a disclosed basis of sufficient facts or data (FRE 705; 37 C.F.R. § 42.65), are not based on sufficient facts or data (FRE 702), and/or are not the product of reliable principles and methods (FRE 702). Additionally, Petitioner objects to the above referenced paragraphs of Exhibit 2053 and all paragraphs that rely on those paragraphs as misleading, incomplete, and lacking relevance and because any probative value is substantially outweighed by the danger of unfair prejudice, confusing the issues, misleading the fact finder, undue delay, wasting time, and needlessly presenting cumulative evidence (FRE 106, 401, 402, and 403).

Petitioner further objects to ¶¶ 1-10, 17-23, 28, 38-40, 48-50 of Exhibit 2053 and all paragraphs of any declaration that rely on those paragraphs. These paragraphs are irrelevant (FRE 401 and 402), and any probative value is

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